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8 **BEFORE THE**
BOARD OF PHARMACY
9 **DEPARTMENT OF CONSUMER AFFAIRS**
STATE OF CALIFORNIA

10 In the Matter of the Accusation Against:
11 **RITE AID 5602; Vickie Le, Pharmacist-In-**
12 **Charge**
1841 East Fourth Street
13 Ontario, CA 91764

Case No. 4872

ACCUSATION

14 Pharmacy Permit No. PHY 42511

15 and

16 **Vickie Le**
1100 Palm Avenue
17 San Gabriel, CA 91776

18 Pharmacist License No. RPH 45667

19 Respondents

20
21 Complainant alleges:

22 **PARTIES**

- 23 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
24 as the Executive Officer of the Board of Pharmacy (Board), Department of Consumer Affairs.
25 2. On or about August 24, 1992, the Board of Pharmacy issued Pharmacist License
26 Number RPH 45667 to Vickie Le (Respondent Le). The Pharmacist License was in full force and
27 effect at all times relevant to the charges herein and will expire on June 30, 2016, unless renewed.
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3. On or about December 23, 1996, the Board of Pharmacy issued Pharmacy Permit Number PHY 42511 to Rite Aid 5602 (Respondent Rite Aid). Vickie Le has been the Pharmacist-in-Charge since March 22, 1999 (collectively, Respondents). The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on April 1, 2015, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 118, subdivision (b), provides in pertinent part that the suspension, expiration, or forfeiture by operation of law of a license issued by a board in the department, or its suspension, forfeiture, or cancellation by order of the board or by order of a court of law, or its surrender without the written consent of the board, shall not, during any period in which it may be renewed, restored, reissued, or reinstated, deprive the board of its authority to institute or continue a disciplinary proceeding against the licensee upon any ground provided by law or to enter an order suspending or revoking the license or otherwise taking disciplinary action against the licensee on any such ground.

6. Section 4300 states, in pertinent part:

“(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its

1 discretion may deem proper.”

2 3 STATUTORY PROVISIONS

4 7. Section 4081, subdivision (a) provides in pertinent part:

5 “All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or
6 dangerous devices shall be at all times during business hours open to inspection by authorized
7 officers of the law, and shall be preserved for at least three years from the date of making. A
8 current inventory shall be kept by every manufacturer, wholesaler, pharmacy ... or establishment
9 holding a currently valid and unrevoked certificate, license, permit, registration, or exemption
10 under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4
11 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who
12 maintains a stock of dangerous drugs or dangerous devices.”

13 8. Section 4301, subdivision (d) provides in pertinent part:

14 “The Board shall take action against any holder of a license who is guilty of
15 unprofessional conduct or whose license has been procured by fraud or misrepresentation or
16 issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the
17 following:

18 ...

19 (d) The clearly excessive furnishing of controlled substances in violation of subdivision
20 (a) of Section 11153 of the Health and Safety Code.”

21 22 REGULATORY PROVISIONS

23 9. California Code of Regulations, Title 16, section 1718 states:

24 “‘Current Inventory’ as used in Sections 4081 and 4332 of the Business and Professions
25 Code shall be considered to include complete accountability for all dangerous drugs handled by
26 every licensee enumerated in Sections 4081 and 4332.

27 The controlled substances inventories required by Title 21, CFR, Section 1304 shall be
28 available for inspection upon request for at least 3 years after the date of the inventory.”

1 10. California Code of Regulations, Title 16, section 1761 states:

2 “(a) No pharmacist shall compound or dispense any prescription which contains any
3 significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any
4 such prescription, the pharmacist shall contact the prescriber to obtain the information needed to
5 validate the prescription.

6 (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense
7 a controlled substance prescription where the pharmacist knows or has objective reason to know
8 that said prescription was not issued for a legitimate medical purpose.”

9
10 **OTHER PROVISIONS**

11 11. Health and Safety Code section 11153, subdivision (a) states in pertinent part:

12 “(a) A prescription for a controlled substance shall only be issued for a legitimate medical
13 purpose by an individual practitioner acting in the usual course of his or her professional practice.
14 The responsibility for the proper prescribing and dispensing of controlled substances is upon the
15 prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the
16 prescription. Except as authorized by this division, the following are not legal prescriptions: (1)
17 an order purporting to be a prescription which is issued not in the usual course of professional
18 treatment or in legitimate and authorized research; or (2) an order for an addict or habitual user of
19 controlled substances, which is issued not in the course of professional treatment or as part of an
20 authorized narcotic treatment program, for the purpose of providing the user with controlled
21 substances, sufficient to keep him or her comfortable by maintaining customary use.”

22
23 **COST RECOVERY**

24 12. Business and Professions Code section 125.3 provides in pertinent part, except as
25 otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before
26 any board within the department or before the Board of Pharmacy upon request of the entity
27 bringing the proceedings, the administrative law judge may direct a licentiate found to have
28 committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable

1 costs of the investigation and enforcement of the case. Nothing in this section shall preclude a
2 board from including the recovery of the costs of investigation and enforcement of a case in any
3 stipulated settlement.

4 DRUG DEFINITIONS

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6 13. **Oxycodone**, is a Schedule II controlled substance pursuant to Health and Safety
7 Code Section 11055(b)(1)(M) and a dangerous drug per Business and Professions Code Section
8 4022.

9 14. **Alprazolam**, is a Schedule IV controlled substance pursuant to Health and Safety
10 Code Section 11057(d)(1) and a dangerous drug per Business and Professions Code Section 4022.

11 15. **Temazepam**, is a Schedule IV controlled substance pursuant to Health and Safety
12 Code Section 11057(d)(29) and a dangerous drug per Business and Professions Code Section
13 4022.

14
15 16. **Oxymorphone**, trade name Opana ER is a Schedule II controlled substance
16 pursuant to Health and Safety Code Section 11055(b)(1)(N) and a dangerous drug per Business
17 and Professions Code Section 4022.

18 BACKGROUND FACTS

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20
21 17. On or around January 11, 2013, Board Inspectors (Inspectors) performed a routine
22 inspection to examine Respondents prescription documents and records based on reports of large
23 amounts of prescriptions being dispensed for oxycodone 30 mg.

24 18. During the inspection, Inspectors noticed a large amount of prescriptions for
25 controlled substances from 'out of the area' patients and doctors.

26 19. On or around March 18, 2013, Respondents produced, upon request, the following
27 documents:

- 28 • A Drug Utilization Report (DUR) for oxycodone 30 mg.

- Drug Enforcement Agency (DEA) inventory dated May 1, 2010 showing that Respondent did not have any oxycodone 30 mg (oxy) in stock.
- DEA inventory dated May 1, 2012 showing that Respondent had 1,061 tablets of oxy in stock.
- Purchase records from Anda¹ which showed that during the time period between May 1, 2010 and March 4, 2013 Respondent purchased 2000 tablets of oxy.
- Purchase records from McKesson² which showed that during the time period between May 1, 2010 and April 16, 2012, Respondent purchased 185,100 tablets of oxy.
- Return records of oxy, showing 1,600 returned tablets.

20. The DUR records demonstrated that during the time period between May 1, 2010 and May 2, 2012, Respondents dispensed 188,295 oxy tablets.

21. The purchase and return records showed that during the time period between May 1, 2010 and May 2, 2012, Respondents purchased 185,500 oxy tablets.

22. Based on DUR records, purchase and return records and DEA inventory records showing stock on hand of 1,061 tablets, Respondents failed to account for 1,734 oxy tablets.

23. Respondents also produced, upon request, a CURES report³ and selected Patient Activity Reports (PARS) for the following patients⁴. The PARS contained the following information:

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¹ Anda distributes generic, select brand pharmaceutical products, vaccines, injectables and over-the-counter medicines from more than 200 suppliers to more than 60,000 locations, including independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains and physicians' offices.

² McKesson supplies branded, generic and over-the-counter pharmaceuticals to more than 40,000 customers spanning retail chains, independent retail pharmacies and institutional providers such as hospitals, health systems, integrated delivery networks and long-term care providers.

³ Controlled Substance Utilization Review and Evaluation System (CURES) is designed to identify and deter drug abuse and diversion through accurate and rapid tracking of Schedule II through IV controlled substances. It is a valuable investigative, preventive and educational tool for law enforcement, regulatory boards, educational researchers, and the healthcare community.

⁴ Initials are used to protect confidentiality.

a. Patient S.A.

Date	Oxy Tablets Received (30 mg)	Rx #	Physician	Location
2/7/11	240	630673	Dr. Garfinkel	Royal Hills
2/9/11	240	800330	Dr. Onubah	Respondent
2/22/11	120	869427	Dr. Lifson	Shalom Pharmacy
3/3/11	240	803651	Dr. Onubah	Respondent
3/20/11	120	873404	Dr. Garfinkel	Royal Hills
4/4/11	240	809644	Dr. Onubah	Respondent

Respondents failed to check the patient profile to discover 8 days early between Rx #800330 and 803651. Respondents also failed to obtain a PAR to discover that S.A. obtained multiple early prescriptions for controlled substances from multiple physicians.

b. Patient W.A.

Date	Tablets Received	Rx #	Physician	Location
2/8/12	60 Alprazolam (.5 mg)	866094	Dr. Makandura	Respondent
2/9/12	60 Alprazolam (.5 mg)	866218	Dr. Makandura	Respondent
6/20/12	30 Temazepam (30 mg)	887926	Dr. Makandura	Respondent
7/11/12	30 Temazepam (30 mg)	887926	Dr. Makandura	Respondent
9/9/12	60 Alprazolam (.5 mg)	905095	Dr. Makandura	Respondent

9/20/12	60 Alprazolam (.5 mg)	907047	Dr. Makandura	Respondent
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Respondents failed to obtain a PAR to discover that W.A. obtained multiple early prescriptions for controlled substances.

c. Patient C.M.

Date	Hydrocodone/APAP Tablets Received	Rx #	Physician	Location
3/28/12	60	1097892	Dr. Santz	Respondent
4/2/12	60	876872	Dr. Santz	Respondent
4/15/12	60	879247	Dr. Santz	Respondent
5/22/12	60	885852	Dr. Santz	Respondent
6/7/12	60	888648	Dr. Santz	Respondent

Respondents failed to obtain a PAR to discover that C.M. obtained multiple early prescriptions for controlled substances.

d. Patient C.M.

Date	OxyContin Tablets Received (80 mg)	Rx #	Physician	Location
1/14/11	60	544898	Dr. Hong	CVS Pharmacy
1/16/11	60	795254	Dr. Hong	Respondent

Respondents failed to obtain a PAR to discover that C.M. obtained an early prescription for controlled substances.

e. Patient R.T.

Date	Tablets Received	Rx #	Physician	Location
7/20/10	60 OxyContin (80 mg)	761507	Dr. Garfinkel	Century Discount Pharmacy
8/3/10	90 OxyContin (80 mg)	766024	Dr. Onubah	Respondent
8/5/11	240 Oxycodone (30 mg)	832146	Dr. Clyde	Respondent
8/31/11	240 Oxycodone	836685	Dr. Clyde	Respondent
1/31/12	180 Oxycodone	864333	Dr. Clyde	Respondent
2/23/12	180 Oxycodone	868670	Dr. Arnold	Respondent

Respondents failed to obtain a PAR to discover that R.T. obtained prescriptions from multiple pharmacies and from multiple doctors during the time period patient was receiving prescriptions from Respondent.

f. Patient A.W.

Date	Tablets Received	Rx #	Physician	Location
1/14/11	240 Oxycodone (30 mg) 20 DS	795027	Dr. Clyde	Respondent
2/14/11	240 Oxycodone (30 mg) 30 DS	801344	Dr. Clyde	Respondent
3/14/11	240 Oxycodone (30 mg) 30 DS	806843	Dr. Clyde	Respondent
4/15/11	240 Oxycodone (30 mg) 20 DS	813054	Dr. Clyde	Respondent

1	5/11/11	240 Oxycodone	817439	Dr. Clyde	Respondent
2		(30 mg) 20 DS			
3	6/20/11	240 Oxycodone	822752	Dr. Clyde	Respondent
4		(30 mg) 20 DS			
5	7/7/11	240 Oxycodone	827152	Dr. Clyde	Respondent
6		(30 mg) 20 DS			
7	8/5/11	240 Oxycodone	832147	Dr. Clyde	Respondent
8		(30 mg) 30 DS			
9	8/31/11	240 Oxycodone	836684	Dr. Clyde	Respondent
10		(30 mg) 30 DS			
11	9/29/11	240 Oxycodone	842172	Dr. Clyde	Respondent
12		(30 mg) 30 DS			
13	10/27/11	240 Oxycodone	847076	Dr. Clyde	Respondent
14		(30 mg) 22 DS			
15	11/15/11	180 Oxycodone	850380	Dr. Clyde	Respondent
16		(30 mg) 30 DS			
17	12/8/11	180 Oxycodone	854516	Dr. Clyde	Respondent
18		(30 mg) 30 DS			
19	1/3/12	180 Oxycodone	859156	Dr. Clyde	Respondent
20		(30 mg) 30 DS			
21	1/31/12	180 Oxycodone	864334	Dr. Clyde	Respondent
22		(30 mg) 30 DS			
23	2/23/12	180 Oxycodone	868672	Dr. Clyde	Respondent
24		(30 mg) 30 DS			
25	6/4/12	90 Oxycodone	887865	Dr. Alav	Respondent
26		(30 mg) 30 DS			
27	7/2/12	90 Oxycodone	893060	Dr. Alav	Respondent
28					

	(30 mg) 30 DS			
9/18/12	60 Oxycodone (10 mg) 15 DS	906170	Dr. Martinez	Respondent
10/17/12	90 Oxycodone (30 mg) 30 DS	911895	Dr. Fok	Respondent
11/19/12	90 Oxycodone (30 mg) 30 DS	917949	Dr. Fok	Respondent
12/12/12	90 Oxycodone (30 mg) 30 DS	921385	Dr. Fok	Respondent
1/10/13	90 Oxycodone (30 mg) 30 DS	926854	Dr. Fok	Respondent
2/8/13	90 Oxycodone (30 mg) 30 DS	933365	Dr. Fok	Respondent
3/5/13	90 Oxycodone (30 mg) 30 DS	938515	Dr. Fok	Respondent
4/5/13	90 Oxycodone (30 mg) 30 DS	944698	Dr. Fok	Respondent
5/3/13	90 Oxycodone (30 mg) 30 DS	950108	Dr. Fok	Respondent

Respondents failed to discover the patient's multiple early orders. Respondents also failed to obtain a PAR to discover that A.W. obtained prescriptions from multiple pharmacies and from multiple doctors during the time period patient was receiving prescriptions from Respondent.

24. On or around 4/14/11, 67 patients came into Respondent pharmacy consecutively, 54 for oxycodone 30 mg and 13 for Opana 40 mg.

25. On or around 3/4/11, 23 patients came into Respondent pharmacy consecutively, 11 for oxycodone 30 mg and 12 for Opana 40 mg.

26. On or around 3/2/11, 32 patients came into Respondent pharmacy consecutively for oxycodone 30 mg.

27. On or around 2/16/11, 13 patients came into Respondent pharmacy consecutively, 10 for oxycodone 30 mg and 3 for Opana 40 mg.

28. On or around 2/14/11, 11 patients came into Respondent pharmacy consecutively for oxycodone 30 mg.

29. On or around 2/8/11, 12 patients came into Respondent pharmacy consecutively, 8 for oxycodone 30 mg and 4 for Opana 40 mg.

30. On or around 2/1/11, 44 patients came into Respondent pharmacy consecutively, 43 for oxycodone 30 mg and 1 for Opana 40 mg.

31. On or around 1/31/11, 10 patients came into Respondent pharmacy consecutively for oxycodone 30 mg.

32. On or around 1/5/11, 14 patients came into Respondent pharmacy consecutively, 10 for oxycodone 30 mg and 4 for Opana 40 mg.

33. On or around 1/4/11, 18 patients came into Respondent pharmacy consecutively for oxycodone 30 mg.

34. On or around 1/3/11, 18 patients came into Respondent pharmacy consecutively for oxycodone 30 mg.

FIRST CAUSE FOR DISCIPLINE

(Filling Irregular and Uncertain Prescriptions)

35. Respondents Rite Aid 5602 and Vickie Le are subject to disciplinary action under Cal. Code of Regs. Title 16, section 1761, subdivisions (a) – (b), in that Respondents filled prescriptions which contained significant irregularities and uncertainties. Complainant incorporates by reference, paragraphs 17 – 34 above, and all subparagraphs as if fully set forth herein.

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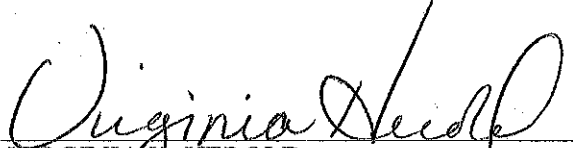
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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board issue a decision:

1. Revoking or suspending Pharmacist License Number RPH 45667 issued to Vickie Le;
2. Revoking or suspending Pharmacy Permit Number PHY 42511, issued to Rite Aid 5602;
3. Ordering Rite Aid 5602 and Vickie Le, Pharmacist-in-Charge, to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;
4. Taking such other and further action as deemed necessary and proper.

DATED; 1/17/15


VIRGINIA K. HEROLD
Executive Officer
California State Board of Pharmacy
State of California
Complainant

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